

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study the effect of local steroid injection on reduction of color of melasma lesion in comparison with Kligman pomad in women with facial melasma

Protocol summary

Summary

Objective: Study the effect of local steroid injection in treatment of melasma. Design: Open label randomized controlled trial. setting: The eligible patients with chronic melasma who will refer to Farshchian Dermatology clinic in 2013. Inclusion criteria: (a) patients with melasma; (b) age between 25 and 40. Exclusion criteria: (a) pregnancy; (b) atrophy in melasma lesion; (c) autoimmune disease; (d) male; (e) telangiectasia in melasma lesion; (f) using oral contraceptive. Intervention: twenty one patients will receive intralesional Triamcinolone injection Spaced 5 millimeters (the concentration of Triamcinolone is 4 milligrams in milliliter). Control: twenty one patients will receive topical formulation (Kligman cream) containing (Tretinoin 0.1 grams, Dexamethasone 0.1 grams, Hydroquinone 5 grams in a cold cream up to 100 grams) every night for two months. Primary outcome: Color changes in lesion. Secondary outcome: Atrophy in lesion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061813699N1**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name

Gholamreza Eshghi

Name of organization / entity

Hamedan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice- chancellor for Research and technology, Hamedan University of Medical Science.

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of local steroid injection on reduction of color of melasma lesion in comparison with Kligman pomad in women with facial melasma

Public title

Study the effect of local steroid injection in treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) patients with melasma; (b) age between 25 and 40. Exclusion criteria: (a) pregnancy; (b) atrophy in melasma lesion; (c) autoimmune disease; (d) male; (e) telangiectasia in melasma lesion; (f) using oral

contraceptive

Age
From **25 years** old to **40 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
On the first visit to the clinic, patients were randomized using a table of random numbers and divided into two intervention and control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Hamedan University of Medical Science

Street address

Hamedan University of Medical Science, Shahid Fahmideh Ave.

City

hamedan

Postal code

6517838695

Approval date

2013-07-04, 1392/04/13

Ethics committee reference number

1043/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Color of Melasma lesion.

Timepoint

Fifteen and 45 days after injection.

Method of measurement

Questionnaire.

Secondary outcomes

1

Description

Atrophy in Melasma lesion.

Timepoint

The first and second months after injections.

Method of measurement

Observation of lesion by researcher.

Intervention groups

1

Description

Intralesional Triamcinolone (Hexal Pharmaceutical company) ampul injection Spaced 5 millimeters (the concentration of Triamcinolone is 4 milligrams in milliliter).

Category

Treatment - Drugs

2

Description

Topical formulation (Cligman cream) containing (Tretinoin 0.1 grams, Dexamethasone 0.1 grams, Hydroquinone 5 grams in a cold cream up to 100 grams) every night one time for two month will be applied on Melasma lesion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchin Hospital

Full name of responsible person

Dr gholamreza Eshghi

Street address

Farshchin Hospital, Mirzadeh Eshghi Ave.

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- chancellor for Research and technology
Hamedan University of Medical Science.

Full name of responsible person

Dr Heydar Tavilani

Street address

Hamedan University of Medical Science, Shahid
Fahmideh Ave.

City

Hamedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice- chancellor for Research and technology Hamedan
University of Medical Science.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Science

Full name of responsible person

Dr Gholamreza Eshghi

Position

Specialist in Dermatology

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty